

REMARKS

The applicants have studied the Final Office Action dated February 11, 2004, and the subsequent Advisory Action dated September 21, 2004. The applicants wishes to thank the Examiner for the telephonic interview on September 8, 2004 informing us about the issuance of the Advisory Action, and the reasons behind the new rejection. In order to continue prosecution of this case, the applicants have filed an RCE along with this Amendment. In this Amendment, the applicants have made amendments to the claims to overcome the concerns of the Examiner. By virtue of this amendment, claims 1-13 and 89-90 are pending and claims 1-13 and 89 have been amended. Amendments to claims 2-13 and 89 were made to place the claims in better form. No substantive changes were intended by the amendments to dependent claims 2-13 and 89. Amendment to claim 1 will be discussed below in more detail. It is respectfully submitted that the application, as amended, is in condition for allowance.

To give some background on this case, Examiner Thissell was initially assigned to handle this application. Prior to Examiner Thissell's departure from the Patent Office, the applicants scheduled and confirmed an interview with Examiner Thissell. Amendments were discussed with Examiner Thissell and he agreed that the case would be allowable with a minor amendment that he would enter as an Examiner's Amendment. He confirmed that he allowed the case and passed it on to his Primary Examiner for issuance of a Notice of Allowance in his April 24, 2004 email. Since that time, Examiner Maiorino has taken over the case for Examiner Thissell. Examiner Maiorino has issued an Advisory Action stating that the amendments agreed to with Examiner Thissell are not sufficient to overcome the rejections based on the Wilson et al reference cited in the Final Office Action.

In the Final Office Action, claims 1-3, 6-11, and 89-90 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,165,407 to Wilson et al. This rejection is respectfully traversed.

Embodiments of the present invention are directed to a sensor with notches cut in the substrate to form a necked down region in the substrate to allow insertion into the skin of a user using a slotted needle. The notches cut in the substrate do not effect the workings of the sensor itself and specifically designed to avoid exposing the electrodes of the sensor. Claim 1 (and thus dependent claims 2-3, 6-11, and 89-90) has been amended to more specifically recite: "a substrate with notches cut in the substrate to form a necked down region in the substrate ... wherein the notches cut in the substrate do not expose any sensor electrode to analytes" (emphasis added). The Wilson et al. reference does not disclose, teach, or suggest a substrate with notches cut in the substrate to form a necked down region in the substrate that does not expose a sensor electrode to analytes.

The Wilson et al. reference describes a sensor where a neck down region is formed to expose the sensor electrode. Specifically, the Wilson et al. reference recites: "The section 10 includes a central platinum-iridium wire 12 (0.18 mm o.d.) and a coating of insulative Teflon 14 (0.035 mm thickness) therearound. The central wire 12 forms the indicating electrode from the sensor. A cavity 16 (1-3 mm in length) is formed in the wire 10 as shown in FIG. 1. This is achieved by first putting a circular cut on the Teflon coating with a paper cutter and then pulling the Teflon out to create a cavity of about 1 millimeter in length, exposing a corresponding section of the wire 12" (see col. 4, line 66 – col. 5, line 7)(emphasis added). The reason the Wilson et al. reference uses a cavity 16 is to expose the sensor electrode is for the very function of the sensor itself. Without exposing the sensor electrode in the Wilson et al. reference sensor, the sensor electrode would not have contact with the environment and thus not be able to function. Cavity 16 of the Wilson et al. reference sole purpose is to expose the sensor electrode to analytes, which opposes the function of the notches cut in the substrate of the present invention. Nowhere in the Wilson et al. reference describes a substrate with notches cut in the substrate to form a necked down region in the substrate that does not expose any sensor electrode to analytes.

It is believed that the Examiner agrees with this interpretation of the Wilson et al. reference. The Examiner only objected to the limitation in the previous version of claim 1,

which stated “do not expose the at least one sensor electrode” (emphasis added). The Examiner explained that this limitation could possibly mean a second sensor electrode can be exposed. To alleviate the Examiner’s concerns, the applicants have amended claim 1 to specifically recite “do not expose any sensor electrode” (emphasis added).

Therefore, it is respectfully submitted that the rejection of claims 1-3, 6-11, and 89-90 under 35 U.S.C. § 102(b) should be withdrawn.

Claims 4 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,165,407 to Wilson et al. in view of U.S. Patent No. 5,390,671 to Lord et al. This rejection is respectfully traversed.

Claims 4 and 5 depend from independent claim 1. Claim 1 has been patentably distinguished over Wilson et al. reference, as discussed above. Accordingly, claims 4 and 5 are also distinguished over the Wilson et al. reference. The Lord et al. reference does not make up the deficiencies of the Wilson et al. reference. In other words, the Lord et al. reference does not disclose, teach, or suggest “a substrate with notches cut in the substrate to form a necked down region in the substrate ... wherein the notches cut in the substrate do not expose any sensor electrode to analytes” (emphasis added) as recited in claim 1. The Lord et al. reference was cited solely for the proposition of teaching the use of a slotted needle. Therefore, it is respectfully submitted that the rejection of claims 4 and 5 under 35 U.S.C. § 103(a) should be withdrawn.

Claims 12 and 13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,165,407 to Wilson et al. in view of U.S. Patent No. 6,256,937 to Schulman et al. This rejection is respectfully traversed.

Claims 12 and 13 and their base claims also depend from independent claim 1. Claim 1 has been patentably distinguished over Wilson et al. reference, as discussed above. Accordingly, claims 12 and 13 are also distinguished over the Wilson et al. reference. The Schulman et al.

reference does not make up the deficiencies of the Wilson et al. reference. In other words, the Schulman et al. reference does not disclose, teach, or suggest "a substrate with notches cut in the substrate to form a necked down region in the substrate ... wherein the notches cut in the substrate do not expose any sensor electrode to analytes" (emphasis added) as recited in claim 1. The Schulman et al. reference was cited solely for the proposition of teaching having electrodes on multiple surfaces. Therefore, it is respectfully submitted that the rejection of claims 12 and 13 under 35 U.S.C. § 103(a) should be withdrawn.

Therefore, in light of the above remarks, it is respectfully submitted that claims 1-13, 89, and 90 are in condition for allowance.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Northridge, California, telephone number (818) 576-4110, to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

Dated: 10/7/04

By: Richard Yoon
Richard Yoon
Reg. No. 42,247

Medtronic MiniMed, Inc.
18000 Devonshire Street
Northridge, CA 91325-1219
Telephone (818) 576-4110
Facsimile (818) 576-6202